

RISKY BUSINESS



What is to be done about chronic health risks posed by human exposure to hazardous substances? How can finite resources be used to assess these risks, set priorities, enact standards, apply incentives, monitor regulatory performance, and achieve a coherent national approach to risk management? How do we make this enterprise effective, efficient, equitable, and science-based, yet fully responsive to people's concerns and the special needs of vulnerable groups? These are some of the tough issues addressed by the Congressionally authorized Commission on Risk Assessment and Risk Management in its June 1996 draft report. The 10-member commission was charged by the Clean Air Act Amendments of 1990 to investigate the policy implications and appropriate uses of risk assessment and risk management in regulatory programs under various federal laws, with an emphasis on preventing cancer and other chronic human health effects that may result from exposure to hazardous substances. Since May 1994, the commission has deliberated, held hearings across the United States, and sought input from a wide range of experts and stakeholders. A final version of the report, entitled *Risk Assessment and Risk Management in Regulatory Decision-Making*, will be provided to Congress, the President, and the public in October 1996.

Responses to the draft credit the commission for its earnest effort and its willingness to sketch out new policy directions, as well as to take a clear stance on some highly controversial issues. But commission findings, rationales, and recommendations on several matters have been faulted by various reviewers on grounds ranging from lack of requisite expertise, to promoting

personal agendas, to offering panaceas without providing necessary scientific analysis and guidance for implementation. The commission intends to respond to this critical feedback in its final report, but points proudly to a recent indicator of Congressional favor with its work the enactment in August 1996 of the Food Quality Protection Act. "The new law replaces the zero-risk Delaney clause with a negligible risk approach, which accommodates special population subsectors, and the commission's report promoting such an approach was cited favorably in the legislative process," according to commission chairman Gilbert Omenn, dean of the School of Public Health at the University of Washington.

New Risk Management Framework

The first major feature of the commission's draft is its brief sketch of a new risk management framework that would address each risk problem in its full environmental and social context. The framework's main purpose is set forth in the report as the need to make more efficient use of limited resources than the "chemical by chemical, medium by medium, risk by risk strategy" now employed by agencies in a "highly fragmented and adversarial system of conflicting actions" because of "multiple, unrelated statutory requirements." The frame-

work also provides a systematic process for integrating public values, perceptions, ethics, and other considerations into risk management decisions. This is consistent with principles of participatory democracy and the need to balance environmental health protection with economic well-being for sustainable development.

The framework comprises six stages, briefly described by the commission.

Formulating the risk problem. This should be done in a "comprehensive, multimedia, public health context" with early involvement of stakeholders and risk managers at federal, state, and local levels to characterize the problem, risk management goals, and objectives. The context of such problems may be national or regional. Within the chosen context, all sources of the pollutant, all pathways of exposure (air, water, food), and a host of sociocultural and economic factors would be evaluated in order to characterize the risk problem for the next stage.

Analyzing the risks. This task is to be done "primarily by scientists and risk managers with input from stakeholders," combining factual and scientific considerations with subjective perceptions. Thus, the risks characterized in the first stage "would be treated both qualitatively and quantitatively."

Defining the options. Options for managing risks by regulatory and nonregulatory means, a process for estimating and comparing risk reductions, costs, and benefits associated with each option, and relevant cultural, ethical, political, and legal dimensions should be defined.

Making sound decisions. Decisions should be made by choosing "the most feasible, effective, acceptable, and cost-effective approaches." A mechanism for conflict

resolution should be used when needed, but when consensus is not achieved, "the responsible regulatory authority must make its decision."

Taking actions to implement the decisions. Such actions should be taken by public agencies, businesses, industries, and private citizens, alone or in combination, as appropriate.

Evaluating the effects of the actions taken. Monitoring and surveillance, discussions with stakeholders, and analyses of relationships between interventions and trends in health or environmental indicators should be used to evaluate the effects of the actions taken; problem definition and actions will be rethought if necessary. This step requires good baseline and surveillance information.

Following this simplistic sketch of six complex procedures, the commission provides ambiguous guidance for using the framework: "The proposed framework is intended to be a guide for an approach or thought process for risk management decision-making. It is unlikely that all aspects of the framework would be required for every problem and some might be inconsistent with certain statutory requirements. Different levels of decision-making will require different levels of analysis. Risk managers should apply this process flexibly to accommodate the needs of individual circumstances." The commission further notes that "full implementation will lead to a need for Congressional authorization and funding; however, much progress can be made with existing statutes."

According to Omenn, the framework "represents a public health approach that cuts through the polarized debate of the last 20 years, providing a risk management approach to public and environmental health risks that is sensitive to susceptible subpopulations and the real costs of compliance. It is logical, based on the views of many people, puts risk problems in their full context, and provides for true two-way risk communication with stakeholders."

Commission member Bernard Goldstein, director of the Environmental and Occupational Health Sciences Institute at Rutgers University, adds, "the framework is intended to move risk management beyond the Beltway to state and local levels, and enhance a regional approach to risk. Stakeholders at the local community level will provide useful information and be involved in framing the issues and responses. The models of community risk now being relied on are inaccurate. We should use our best tools to estimate risks more accurately and respond to local concerns. These tools include bio-

markers and biomonitoring using, for example, human tissue and fluid samples to determine exposure and early effects. The framework also calls for an evaluation function to be built into every regulatory program—an important function not being done at the present."

One supporter of the new framework is the American Industrial Health Council (AIHC), a broad-based industry association. In comments on the draft report, the AIHC endorses the iterative feature of the framework: "Maintaining the option, when circumstances justify, to reiterate the entire cycle . . . is a logical plan by which to assure that more effective and efficient decisions are made, and less effective/efficient ones are identified."

Adam Finkel, the Occupational Safety and Health Administration's director of health standards, agrees that it makes sense to look at exposures and risks in context, but expresses concern that "using framework procedures to prioritize risks could result in neglecting other important risks [that] would be relatively easy to control." Finkel adds a larger concern that "the framework and the report promote a public health approach, shaped by economic efficiency considerations, to deal with population and subpopulation risks in various contexts. This approach could displace current efforts to use a balanced approach for finding appropriate solutions to individual risks."

Additional reservations have been expressed by Robin Cantor, program director for decision, risk, and management sciences at the National Science Foundation. Cantor, a member of a risk assessment subcommittee of the National Science and Technology Council, characterizes the report and its framework as "reflecting good intentions but leaping to recommen-

for the new framework as an improvement over current practices, probably because commission members were not sufficiently familiar with current efforts and practices by federal agencies in the areas of risk assessment and risk management.

Reviewers of the report also find that the framework proposal neglects some obvious institutional and policy issues. For example, existing laws are quite prescriptive and would obstruct implementation of the proposed approach since agency authority is limited to statutory mandate. Thus, major Congressional reforms and intricate interagency cooperation would be needed for full implementation. Then there is the considerable problem of defining risk contexts and dealing with the foreseeable conflicts over context boundaries. Related to this problem is another issue: whether states and communities have the will, resources, and expertise to carry out their proposed roles.

Another problem is how to ensure that the same risk decisions are made in each of several contexts for the same risk problem; differential outcomes could serve as incentives for industry to relocate to the more permissive contexts, causing economic and social dislocations. And there is the considerable task of creating the new institutional arrangements, infrastructures, and enforcement mechanisms that would be needed for regional risk contexts. This could easily become a costly, time-consuming, and even impossible task. Thus, each proposed solution leads to a multiplicity of new problems. The final report may address some of these questions.

Risk Assessment

The second major feature of the draft report is its analysis and recommendations on the use of risk assessment in regulatory

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dations, attempting to capture a lot of the thinking about risk management of the last 15 years without adequate treatment of the social science issues involved, and calling for panaceas such as stakeholder involvement and biomonitoring without seriously addressing the issues these [suggestions] raise." Others have voiced the comment that the report fails to provide justification

decision-making. This chapter addresses toxicity assessment, exposure assessment, uncertainties in risk estimation and reduction, chemical mixtures, ecological risk assessment, and radiation and microbial risk assessments.

The section on toxicity assessment is most notable for its implications and controversial recommendations. In it, the

commission reports that chemicals suspected of causing cancer are regulated by assuming that every exposure has some risk, but that chemicals suspected of causing other effects, such as developmental or reproductive toxicity, are regulated by assuming that there is a safe level of exposure. The report asserts that this "simple

tion in the draft report, Omenn and Goldstein indicate that they support present agency approaches, but want agencies to begin exploring the MOE approach. They point to the EPA's newly proposed guidelines for carcinogens with nonlinear dose-response characteristics, which adopt the MOE approach; the suitability of

supportable." Melnick is concerned that "the fixation on specific points in an MOE, such as the 'no observable effects level' (NOEL) used in the ratio, prevents capture of experimental data on dose-response relationships and causes loss of important information on low-dose risk."

Frank Mirer, director of health and safety at the United Auto Workers, worries about the report's focus on noncancer endpoints. "The report expresses concern that too much is being done to address carcinogens and not enough about other risks. But instead of calling for more emphasis on the other risks, it proposes that less be done on carcinogens. It undermines what's been done without putting forth a constructive alternative."

Similar controversy has arisen over another recommendation in the report that certain rodent bioassays indicating rodent cancer responses "be classified as irrelevant to human cancer risk assessment" when testing indicates that the chemical involved produces "only tumors that occur as a result of mechanisms or doses that would have been deemed not relevant to humans." This recommendation also calls for agencies to develop consistent criteria for making such findings, and appends a table of "rodent tumor mechanisms not likely to be relevant to human cancer risk if they are the only responses observed and are due to the mechanisms listed." The table lists several sites of rodent tumors, the mechanisms for such tumors in rodents that are not likely to be relevant to human cancer risk, and the chemicals implicated in causing tumors by such mechanisms.

Comments on this part of the report and its table have been critical, and Omenn indicates that it will be revised in the final report. UAW comments object to such recommendations on toxicity assessment, calling them a form of "super rule-making without an adequate record of data considered." The UAW also says that the chapter's "sweeping statements" will distort agency actions, and objects "most notably" to the commission's discounting of lung tumors based on the overwhelming clearance mechanisms. "The database related to this issue is vast, involving both laboratory and epidemiology studies of substances ranging from cigarette smoke, coke oven emissions, asbestos, silica, talc, carbon black, diesel particulate, and others," reads the UAW commentary. "The hypothesis that lung tumors arise from overwhelming clearance mechanisms is vague, changeable depending on context and interest. Whatever version of this hypothesis is being proposed . . . is not stated and therefore can't be responded to."

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dichotomy is not fully supportable by current scientific evidence," and leads to non-comparable risk assessments and "striking discrepancies among maximal exposures considered to have negligible risk." The discrepancies confound efforts in the areas of comparative risk assessment, risk characterization, and risk communication.

Based on these findings, the commission recommends a consistent margin of exposure (MOE) approach to both categories of chemical risks—chemicals that are proven or suspected of being carcinogens and chemicals that are known or suspected of causing other noncancer effects such as reproductive or neurological toxicity—with the MOE being the ratio of the chemical exposure scientifically predicted to cause a harmful health effect divided by the current actual (or anticipated) human exposure to that chemical. The risk manager, armed with the MOE, would then decide whether the particular ratio provides an appropriate level of protection and, the commission adds, "stakeholders can make their own judgments."

Multiple benefits would arise from using MOEs, according to the commission. It would lessen reliance on low dose-response models, which are based on little data and heroic assumptions. It would also illuminate and make transparent the dichotomy between science and values in choosing a level of protection. It would enhance risk communication on cancer risks that have been heretofore "expressed in a manner that implies an unwarranted degree of precision," as well as stimulate greater emphasis on noncarcinogens. Finally, it would make it easier to compare cancer risks to noncancer risks for making risk management decisions. Citing the urgent need to override the default assumptions used to estimate small risks, the commission is hopeful that biologic markers of early effects will provide a better basis for relating animal and human responses at low doses.

Although prescribed as a recommenda-

MOEs for risk-managing hazardous air pollutants; and MOE potential for providing a common metric that would enhance risk communication and risk comparison.

Finkel contends, however, that "[an] MOE is merely a descriptive statistical presentation or packaging, not a true risk management criterion of scientific value, and runs counter to the views and methods of the scientific community. We have the ability to extrapolate to low exposure levels and estimate carcinogenic risk, and scientists have become more comfortable about doing this. Why use MOE, a lowest common denominator or reductionist approach, which would discard or devalue years of experience in carcinogenic low-dose risk assessment and replace it with the less advanced principles of noncarcinogenic low-dose risk assessment? Why not try to make the less-good better? Furthermore, MOEs are of dubious value for meaningful risk communication, for advancing stakeholder understanding. Indeed, they are quite manipulatable and could mislead stakeholders."

Ronald Melnick, an NIEHS toxicologist currently serving as the institute's representative to the Office of Science and Technology Policy, concurs with Finkel's assessment, and questions whether, "as a statistical presentation designed to facilitate risk communication," the discussion of MOEs would be more appropriate in the report's section on risk communication. At the same time, he asserts that the MOE does not improve risk communication. "The MOE for a potent carcinogen may be small," says Melnick, "but large for a weak carcinogen. How does this improve stakeholder understanding?" Melnick asks, "If a common metric of scientific value is being sought, why not recommend a common approach based on biological mechanisms of action; in other words, use a linear dose-response approach for carcinogens and noncarcinogens when research indicates linear response and, similarly, use a threshold approach for both when this is scientifically

Melnick believes that “the commission jumped too quickly to eliminate rodent tumor responses for lack of human relevance. What’s needed is a scientifically principled guidance instead of the table, which contains inaccuracies. For example, several of the entries can’t be justified as the only responses observed due to the mechanisms listed, and the so called mechanisms are really chemical exposure effects, not mechanisms from a biologic viewpoint. Agencies need more in-depth, scientific evaluation and are unlikely to rely on such a table for risk regulation purposes.”

Melnick adds the further criticism that while the report focuses solely on how mechanistic data may be used to downgrade the results of animal experiments, it fails to acknowledge that such data can be used to identify chemicals as potentially carcinogenic to humans even in the absence of tumor data, to establish risk, and identify sensitive subpopulations.

Among other recommendations on using risk assessment, the commission suggests replacing reliance on the hypothetical maximally exposed individual with “a maximally exposed actual person and estimates of the total number of potentially exposed people in the geographical areas of interest,” or, alternatively, with the EPA’s “high-end exposure estimate” approach. It also recommends that risk assessments include consideration of genetic and other host differences in susceptibility and identify especially susceptible human subpopulations for specific chemical exposures, as well as particular groups of people who are likely to have higher exposures to the chemicals.

As for uncertainty in estimating risk due to gaps in information about scientifically observable phenomena, the commission finds that “quantitative approaches to uncertainty analysis are complex, difficult to perform, difficult to understand, and often unnecessary.” It consequently recommends that “qualitative descriptions of the primary sources of uncertainty . . . be included in risk characterizations intended for risk managers and the nontechnical public . . . with formal quantitative analysis not needed in most risk assessments.” Some reviewers of the report have taken issue with this section because although it discusses types of information the commission feels may be ignored, it fails to provide guidance for strengthening the scientific basis for risk assessments. Others have countered though that the commission may believe that the report’s emphasis on scientific judgment and peer-review adequately address such concerns.

The commission also grapples with risk assessment of chemical mixtures such as

diesel exhaust. It finds that most risk assessments focus on individual chemicals in a particular multichemical exposure context, and simply add them together to estimate risk related to the entire mixture, ignoring synergistic or antagonistic interactions that could underestimate or overestimate total risk. To remedy this situation, the report recommends toxicity testing of such mixtures, with risk adding to be done only when mixtures involve multiple chemical exposures at low concentrations, and information on the mechanisms is either lacking or indicates that the same mechanism of action is involved for each chemical in the mixture. The AIHC emphatically supports this recommendation.

The commission then hurries through the *terra incognita* of ecological risk assessment by endorsing the EPA’s framework for evaluating ecological risk, pausing only to call for interagency collaboration on standardization by developing “clear guidance,” and the addition of stakeholder involvement. The AIHC has registered its disappointment that the “report does not engage in a robust and comprehensive discussion” of this subject. Because “ecological risk assessment deserves more evaluation and discussion,” the AIHC offers some recommendations. For example, the commission should recommend the development of guidance on how to conduct a tiered, iterative approach, and should emphasize that a risk management decision is never final or complete.

George Lucier, director of the Environmental Toxicology Program at the NIEHS, assesses the treatment of ecological risk assessment by the commission as “very superficial, probably because of a lack of ecological experts on the commission.” He adds that “the point needs to be made that, although human health and ecologi-

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cal health have distinct features and problems, there is common ground. This common ground should be probed, not ignored. For example, effects on wildlife and ecological balance may provide harbingers of concern for people. Likewise, the movement and fate of chemicals in the environment may [be] essential tools for estimating the magnitude and duration of human exposure.”

Economic Analysis

A third major feature of the draft report is the use and limitations of economic analysis in regulatory decisionmaking, a subject The commission was not explicitly mandated to address. Finding that full quantification in dollar values is difficult, if not impossible, and that there is concern that regulatory decisions about health and environmental protection might be made strictly on a monetized, cost–benefit basis, the commission takes a mainstream position.

Its recommendation, which Omenn describes as “fitting squarely within the positions of the last five administrations, as expressed in their Executive Orders,” calls for recognition that the tools of economic analysis provide “legitimate and useful ways to obtain information for the risk management framework and regulatory decisions . . . but not as the sole or overriding determinant of those regulatory decisions.” In addition, the report states that “costs and benefits that cannot be assigned monetary values should be addressed and considered explicitly . . . [and that] assumptions should be specified.” The text amplifies this recommendation with a call for supplementing cost–benefit analysis with “information on its distributional consequences,” a point driven home in a second recommendation that economic analysis address any inequitable distributions of costs and benefits, albeit not necessarily in a quantitative fashion. The commission also calls for peer-review of any economic analyses—a measure applauded by many.

A special feature of the discussion is the commission’s comparative evaluation of cost-effectiveness analysis (CEA—used to find the least costly method for achieving a given goal) and cost–benefit analysis

(CBA—used to help find the goal itself). Noting that CEA has the advantage of not requiring monetized benefits, The report nevertheless faults this approach for its inability to “inform the debate over the goals of a policy,” or deal with options that produce differential benefits.

Of course, there is no way to address the use of economic analysis in health and environmental risk management contexts

without controversy. Certain statutes make it impermissible to rely on a CBA approach for setting standards, despite Executive Orders and Office of Management and Budget procedures. Experience has shown that the mainstream policy of merely warning against conclusive use of CBA in regulatory decision-making is insufficient to prevent agency over-reliance on arbitrarily monetized CBA in setting standards. And, if the new framework pro-

report finds that the current use of quantitative estimates for small risks "convey[s] an unwarranted sense of precision while failing to convey the range of scientific opinion." The report goes on to say that such estimates are particularly difficult for nontechnical audiences to comprehend, especially when they reflect uncertainty. Such characterizations may lead only to a demand for more information.

Because of these findings, the commis-

ing a large body of research, they have failed to address the many important issues involved in appropriate use of such communications and comparisons. They simply did not address these subjects in a serious social scientific manner. For example, economists assume consumer sovereignty and individual choice in doing cost-benefit analysis, yet risk managers promote institutional sovereignty when people don't behave rationally. How should these conflicting perspectives within the risk management framework be resolved?"

Possibly the most controversial recommendation in this chapter is the commission's call for bright lines, or single point estimates of risk to judge safety. Acknowledging that bright lines have been criticized as "magic numbers whose use is inconsistent with knowledge about the distributions of risk and their inherent uncertainty" in a 1994 report by the National Research Council, the commission nevertheless finds that bright lines can be useful in guiding a decision process. The recommendation calls for the development of bright lines to protect the general population and additional bright lines for especially susceptible subpopulations such as young children, pregnant women, or adults with particular diseases.

Permissible exposure levels, threshold limit values, action levels for food contaminants, and National Ambient Air Quality Standards for carbon monoxide and other pollutants are cited as effective examples of bright lines. According to the report, these standards "provide assurance that risks will be negligible as long as contaminant exposure concentrations are below the bright lines," and provide a basis for consistent decision-making.

The chapter does address some of the problems associated with the use of bright lines, including the fact that bright lines could be misconstrued as indicating that an exact boundary exists between safety and risk. Bright lines could also be used inflexibly in situations that call for recognition of the unique characteristics of a particular population. Another problem discussed is that point estimates do not reflect any of the uncertainties and assumptions involved in setting bright lines.

To avoid some of the risks of bright lines, the recommendation cautions against inflexible application, proposes multiple bright lines for special population groups, and asks Congress to leave the setting of bright lines to federal agencies, as legislated lines would be inflexible. The report also advises the further precautions that bright lines not be the sole determinants of deci-

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motes stakeholder involvement and qualitative expressions of concern for characterizing risks and setting risk management goals, and MOEs facilitate public selection of levels of protection, the question becomes whether CBA is really needed as a goal-setting tool or, given the targets and goals set by this process, whether CEA is the more appropriate tool.

Concluding the section on economic analysis, the commission recommends that uncertainties be stated explicitly and quantified where appropriate, that results not be expressed as precise measures of actual costs and benefits, that federal guidelines be developed for benefit valuation, and that collaboration between risk assessors and economists be improved in order to minimize inconsistencies between their respective approaches to characterizing and reducing risks.

Risk Management and Regulation

The report's chapter on risk management and regulatory decision-making summarizes methods for characterizing risk and communicating it to stakeholders, comparing risk for various purposes, using bright line rules to expedite risk management, avoiding command and control regulatory implementation, installing peer review, and commenting on judicial review. In this section, the commission finetunes its recommendations to assure that the report's vision will be smoothly implemented.

At the outset, the commission returns to the subject of risk characterization and how to present risk assessment findings to stakeholders, and reinforces the idea of using an MOE approach to emphasize nonprobabilistic expressions of risk. The

commission recommends inclusion of qualitative information on the nature of adverse effects and the risk assessment itself in risk characterizations, along with quantitative estimates, the range of informed views, and their evidentiary support. To prevent the use of data gathering as a delaying or obstructionist tactic, it also recommends that criteria for acquiring additional information be set by all participants in the first stage of managing a risk.

The report then discusses methods of communicating risk information. Citing various studies on risk communication and perception, it finds that trust is a key to effective communication and that industry collaboration with community groups, such as industry-supported citizen advisory panels, is a particularly effective way to build partnerships. A recommendation follows for regulatory agencies to adopt "comprehensive risk communication programs that emphasize both the learning and explaining activities of communication."

The report's rationale for adopting risk communication programs is that the public should more readily accept risk characterizations and regulatory assessments. This raises questions about the nature of such risk communication: should it be used to educate people about how to think about risk, or should it be used to teach people what to think about risk?

Cantor views the commission's treatment of risk communication, and subsequently of risk comparison, as inadequate. "They present these subjects as panaceas for many of the problems [that] afflict risk management, but lacking expertise in the social and behavioral sciences, and neglect-

sion outcomes and that contaminant concentration bright lines are preferable to bright lines expressed as risks because they are easier to implement.

"We have to draw lines in the real world," Omenn says. "When we can't measure risk levels, or set risk levels capable of being monitored, we should set contaminant levels." Goldstein adds that bright lines need not be drawn at a science-based *de minimis* risk level and that the capability of analytic methods or instrumentation will determine the enforceability of a bright line.

The AIHC has expressed concern over what it feels is significant confusion in the report: that its discussion treats bright lines as virtual standards for chemical concentrations, a use that would be inconsistent with the procedures set forth earlier in the commission's new framework. The organization urges the commission to clarify that bright lines be used "only in screening analyses to determine whether more detailed risk assessment is required . . . [and that they] not be construed to be the basis of standards in regulatory decision-making."

Others are also concerned about the prospect that virtual standards in the form of bright lines will emerge from agencies outside of the normal administrative procedures for standard-setting. The UAW objects to such "super rulemaking" aspects of the report, and Melnick expresses concern that the combination of bright lines and MOEs "will have the effect of masking the complexities of risk characterization."

Recommendations for Specific Agency Programs

The commission concludes the draft with an uneven analysis of several agency programs. Little attention is given to some major agencies with big risk management problems. Indeed, the most environmentally troublesome, resource-consuming agencies—the Departments of Energy and Defense—receive the fullest endorsements. The DOE is told only that its efforts "to learn to assess and manage the entire environmental program from a risk perspective should be continued and should be examined as a model for the EPA Superfund program." Many question whether this is adequate guidance for an agency whose programs cover 130 facilities in over 30 states, including many contamination-plagued sites. The DOD, with the massive job of dealing with some 28,000 potentially contaminated sites, receives only the recommendation that it "continue its efforts to establish risk-based remediation priorities among its contaminated sites in collaboration with community advisory groups."

OSHA, with some of the most immediate and serious health risks and resource constraints, receives a familiar message: to work more closely with its research counterpart, National Institute of Occupational Safety and Health, so that its regulatory needs are better served by NIOSH research. But the commission also recommends that OSHA enact default guidelines on several matters, including its methods for assessing noncancer risks, for quantifying and expressing uncertainty and individual variability in risk, and for defining negligible levels of individual risk for various adverse health effects. In comments to the commission, the UAW calls these recommendations limited and disappointing.

More attention is given to the EPA's water, pesticide, and Superfund programs. For example, recommendations include development of an "integrated watershed-management approach," and state watershed programs that provide for stakeholder involvement. Such reforms are consistent with the commission's new framework for looking at risks in a regional context.

The centerpiece of the commission's labors over agency programs is its proposal for EPA implementation of Section 112 of the Clean Air Act, which since 1990 has provided that the agency enact maximum available control technology (MACT) standards for point sources of hazardous air pollutants. This technology-based approach to the longstanding problem of hazardous air pollutants will be supplemented with new EPA risk-based standards for the residual risks that remain after MACT standards are in place. As of May 1996, the EPA had enacted 27 MACT standards, and had started work on identifying and estimating residual risks.

The commission's recommendations focus on the residual risks and strive to create a risk management strategy that will avoid "devoting extensive resources to pollution controls where there are no important risks." The main feature of the recommended strategy is use of a tiered scheme to "characterize and articulate the scope of the national, regional, and local air toxics problems and their public health and environmental contexts; obtain necessary data and perform screening risk assessments to identify sources with the highest risks; conduct more detailed risk assessments of sources and facilities with the highest risks; evaluate risk reduction options at [such facilities]; . . . and determine the need to evaluate residual risks from less high-risk source categories."

Summary

In prior studies by high-level commissions, emphasis was given to improving the scientific basis and institutional procedures for risk assessment and risk regulation within existing statutory frameworks. Recommendations have led to slow but steady progress.

This study is considerably different. It emphasizes a public health approach for efficient use of resources in a new flexible framework for risk management, reductionist approaches to risk assessment and characterization, increased public involvement, and various methods for managing such public involvement. It provides a mix of aspirations and concepts, procedures, and "shop floor rules" for putting the new system of risk management into practice.

Concerns remain, however, that bright lines and other rules are at odds with the report's professed aspirations for meaningful public involvement; that *ad hoc* institutional arrangements for putting each risk in a situational context may not be an efficient use of public and private resources; that techniques for managing stakeholder involvement will be seen as manipulative and may even increase public mistrust and anxieties about risk; and that reductionism by the regulatory clients of risk assessment could diminish progress in the environmental health sciences.

Says Lucier, "The goal of risk assessment should be to prevent environmentally or occupationally mediated diseases or injury. This point is not made sufficiently clear in the commission's report. Nevertheless, the report does an admirable job of attempting to merge science, common sense, public perception, public health, economics, and stakeholder interests into a regulatory policy strategy." He continues, "The merging of these diverse inputs will never be easy and should never be overly prescriptive. The complete integration of all relevant information into the risk assessment and risk management process will require greater reliance on expert judgment to make decisions that are timely, that are based on appropriate peer review, that are consistent with public health priorities, that do not create unnecessary regulatory burdens, and that are understandable by the public."

The commission's report provides an alternative vision of risk management that incorporates popular political and social trends. Thorough evaluation of the report's recommendations will, at the very least, focus scrutiny on current risk assessment and risk management practices and perhaps produce better solutions.

Michael Baram